

cont
A1
container whilst maintaining the sealing ring in sealed contact with the sealing face;
introducing a flowable material into the container through the tubular body;
reinserting the plug into the tubular body to thereby close the tubular body; and
disengaging the sterilization and filling head and the tubular body from each other.--.

IN THE CLAIMS:

Please amend claims 1, 3 to 7, 10 to 17, 19 to 30, 35, 37, 38 and 40
without prejudice as follows, and please add new claims 41 to 60:

1. (Amended) A method of aseptically filling an internally sterilized sealed
container having a transfer port which comprises a tubular body which is sealed to
the wall of the container and defines a flow passage therethrough, and a sealing
plug engaged into the passage, the tubular body having an annular outer sealing
face thereon which surrounds the flow passage, the method comprising the steps of:
supporting the tubular body of the container in a selected orientation and
position;
providing a sterilization and filling head having at least an outer sealing ring
thereon which is adapted to engage and seal with the annular sealing face, and a
sterilization chamber located inwardly of and at least partially defined by the outer
sealing ring;
bringing the sterilization and filling head and the tubular body into
engagement with each other so that the outer sealing ring engages and seals with
the annular sealing face;
introducing a sterilization fluid into the sterilization chamber to sterilize at least
the radially outer part of the plug and that part of the tubular body within the outer
sealing ring;
withdrawing the plug out of the tubular body in a direction away from the
container whilst maintaining the sealing ring in sealed contact with the sealing face;
introducing a flowable material into the container through the tubular body;
reinserting the plug into the tubular body to thereby close the tubular body;
and
disengaging the sterilization and filling head and the tubular body from each
other.

A 3 3. (Amended) A method as claimed in claim 1, wherein the method includes the steps of:

providing a gripping jaw on the sterilization and filling head within the outer sealing ring; and

gripping the plug with the gripping jaw in order to withdraw the plug from the tubular body.

4. (Amended) A method as claimed in claim 2, wherein said method includes the steps of:

maintaining the outer sealing ring in sealing engagement with the annular sealing face on the body; and the inner sealing ring in sealing engagement with the sealing face on the plug;

gripping the plug with the gripping jaw; and

extracting the plug from the tubular body whilst maintaining the inner sealing ring in sealing engagement with the sealing face on the plug.

5. (Amended) A method as claimed in claim 1, wherein the method includes the steps of:

partially inserting the plug into the tubular body;

cleaning the peripheral outer surfaces of the plug prior to fully inserting the plug into the tubular body; and

fully inserting the plug into the tubular body.

6. (Amended) A method as claimed in claim 5, wherein the step of cleaning the peripheral outer surfaces of the plug is achieved by introducing a sterilization fluid into the sterilization chamber with the plug partially inserted into the flow passage in the tubular body.

7. (Amended) A method as claimed in claim 1, wherein the method includes the step of sealing the plug to the tubular body during or after the plug has been reinserted into the tubular body.

A 4 10. (Amended) A sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage

therethrough and a plug for closing the flow passage, at least the tubular body having an annular sealing face thereon, the apparatus comprising:

holding means for holding the container and/or the tubular body in a selected position;

a sterilization and filling head having at least an outer annular sealing ring adapted to engage the annular sealing face on the tubular body and an inner sealing ring located inwardly of the outer sealing ring, the sterilization and filling head having a sterilization chamber located between and at least partially defined by the outer and inner sealing rings, the sterilization and filling head having a cavity therein adapted to receive the plug of a container to be filled, the sterilization and filling head and/or the tubular body being movable towards and away from the other;

sterilization fluid supply means adapted to supply sterilization fluid to the sterilization chamber;

a plug extractor adapted to extract the plug from the tubular body and to move the plug into the cavity in the sterilization and filling head; and

filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted.

11. (Amended) A sterilization and filling apparatus as claimed in claim 10, wherein the inner sealing ring is co-axial with said outer sealing ring and spaced inwardly therefrom to define an annular space therebetween, said annular space forming said sterilization chamber, and said inner sealing ring being engageable with a sealing face provided on the plug.

12. (Amended) A sterilization and filling apparatus as claimed in 10, wherein the plug extractor may comprise one or more gripping jaws adapted to grip the plug and extract it from the tubular body into the cavity.

13. (Amended) A sterilization and filling apparatus as claimed in claim 12, wherein the jaws are mounted to a ram which is moveable in an axial direction towards and away from the plug, the jaws being moveable between gripping and release positions.

14. (Amended) A sterilization and filling apparatus as claimed in claim 13, wherein the jaws automatically move to a gripping position when the ram moves in a direction away from the plug, and move into the release position when the ram moves towards the plug.

15. (Amended) A sterilization and filling apparatus as claimed in claim 13, wherein the ram is adapted to drive the plug into the tubular passage after the container has been filled.

16. (Amended) A sterilization and filling apparatus as claimed in claim 15, wherein the sterilization and filling head is adapted to shut off the flow of filling material into the container prior to the plug being fully inserted into the tubular passage.

17. (Amended) A sterilization and filling apparatus as claimed in claim 15, wherein said sterilization and filling head is adapted to clean the plug with sterilization fluid when the plug is partially re-inserted back into the tubular passage.

20. (Amended) An aseptic container as claimed in claim 18, wherein the gripping formations will allow the application of a rotational force to be applied to the plug to remove or re-install the plug into the filling opening.

21. (Amended) An aseptic container as claimed in claim 18, wherein the plug is removed and reinstalled into said opening by axial means, and said retaining means provide an interference fit.

22. (Amended) An aseptic container as claimed in claim 18, wherein said plug and opening include a screw thread or cam or bayonet locking means.

23. (Amended) An aseptic container as claimed in claim 18, wherein the plug is cup shaped having an end wall and a cylindrical skirt depending from the end wall, the end wall adapted to be outermost when the plug is inserted into the flow passage.

24. (Amended) An aseptic container as claimed in claim 23, wherein the gripping formations are formed on the end wall and project in a direction which is opposite to that in which the skirt extends from the end wall.

25. (Amended) An aseptic container as claimed in claim 24, wherein said gripping formations take the form of a head which stands proud of the end wall.

26. (Amended) An aseptic container as claimed in claim 25, wherein said head is undercut to provide purchase for gripping jaws which are adapted to extract the plug from the flow passage.

27. (Amended) An aseptic container as claimed in claim 18, wherein said locking formations comprise a radially outwardly projecting annular rib formed on the plug, said rib being adapted to be located behind a shoulder, end face or within a groove formed in or adjacent the flow passage.

28. (Amended) An aseptic container as claimed in claim 18, wherein said flow passage and/or the plug have an annular seal therein adapted to seal with a plug inserted into the flow passage.

29. (Amended) An aseptic container as claimed in claim 18, wherein the plug and/or the tubular body are formed of a thermoplastic material adapted to bond together under temperatures of between about 130 °C and 180 °C.

30. (Amended) An aseptic container as claimed in claim 18, wherein the plug and the tubular body are sealed together during manufacture.

35. (Amended) A plug and gland as claimed in claim 34, wherein said sealing ring is a low melt sealant deposited in said recess.

37. (Amended) A plug and gland as claimed in claim 33, wherein the annular recess on the plug is spaced a second distance away from operative outer end face of the tubular body.

38. (Amended) A plug and gland as claimed in claim 33, wherein said plug has a second annular recess formed around the periphery thereof, said second annular recess being spaced from the first annular recess, the second annular recess being spaced a distance away from the operatively outer end face of the plug by a distance which is substantially the same as distance which the rib or lip is spaced away from the operatively outer end face of the gland so that when the rib or lip is located within the second annular recess the operatively outer end faces of the gland and the plug are substantially flush with each other.

40. (Amended) A plug and gland as claimed in claim 33, wherein said rib or lip has a generally triangular form in cross section so as to provide a chamfered or bevelled face in both an outwardly facing direction and an inwardly facing direction to allow for simplified engagement and disengagement of the plug with the gland.

41. (New) A method of aseptically filling an internally sterilized sealed container from a sterilizing and filling head through a transfer port of the container, the transfer port comprising a tubular body sealed to a wall of the container and defining a flow passage therethrough, and a removable sealing plug engaged in said flow passage and having an annular sealing face, the tubular body having an exterior sealing surface, and the sterilization and filling head comprising an outer sealing ring and an inner sealing ring, the method comprising :

supporting the tubular body of the container in a selected orientation and position;

bringing the sterilization and filling head into engagement with the container such that the outer sealing ring engages and seals with the sealing surface of the tubular body and the inner sealing ring engages and seals with the annular sealing face of the plug such that the inner and outer sealing rings and the portion of the transfer port extending therebetween at least partially define a sterilization chamber;

introducing a sterilization fluid into the sterilization chamber;

withdrawing the plug out of the tubular body whilst maintaining the outer sealing ring in sealed contact with the tubular body and whilst maintaining the inner sealing ring in sealed contact with the plug;

introducing a flowable material into the container through the tubular body;

reinserting the plug into the tubular body to thereby close the tubular body;
and
disengaging the sterilization and filling head from the container.

Cont
A9
42. (New) A method of aseptically filling an internally sterilized sealed container from a sterilizing and filling head through a transfer port of the container, the transfer port comprising a tubular body sealed to a wall of the container and defining a flow passage therethrough, and a removable sealing plug sealing said flow passage, the sealing plug having a side wall engaged into the passage, the tubular body having an exterior sealing surface, the sterilization and filling head including an outer sealing ring, the method comprising :

supporting the tubular body of the container in a selected orientation and position;

bringing the sterilization and filling head into engagement with the container such that the outer sealing ring engages and seals with the sealing surface of the tubular body, the portion of the transfer port within the outer sealing ring providing a surface of a sterilization chamber;

introducing a sterilization fluid into the sterilization chamber to sterilize the surfaces of the sterilization chamber;

withdrawing the plug out of the tubular body whilst maintaining the outer sealing ring in sealed contact with the tubular body;

introducing a flowable material into the container through the tubular body;
partially reinserting the plug into the tubular body such that a portion of the plug side wall remains exposed to the sterilization chamber;

cleaning the exposed surfaces of the partially inserted plug;

completing the insertion of the plug into the tubular body to thereby close the tubular body; and

disengaging the sterilization and filling head from the container.

43. (New) A method of aseptically filling an internally sterilized sealed container from a sterilizing and filling head through a transfer port of the container, the transfer port comprising a tubular body sealed to a wall of the container and defining a flow passage therethrough, and a removable sealing plug engaged into the passage in an initial rupturable sealed position, the tubular body having an

exterior sealing surface, the sterilization and filling head comprising an outer sealing ring, the method comprising :

supporting the tubular body of the container in a selected orientation and position;

bringing the sterilization and filling head into engagement with the container such that the outer sealing ring engages and seals with the sealing surface of the tubular body, a portion of the transfer port within the outer sealing ring providing a surface of a sterilization chamber;

introducing a sterilization fluid into the sterilization chamber to sterilize the surfaces of the sterilization chamber;

withdrawing the plug out of the tubular body whilst maintaining the outer sealing ring in sealed contact with the tubular body;

introducing a flowable material into the container through the tubular body;

reinserting the plug into the tubular body into a second position deeper than the initial position to thereby seal closed the tubular body; and

disengaging the sterilization and filling head from the container.

44. (New) A sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage therethrough and a plug for sealing closed the flow passage, the tubular body having an exterior sealing surface, the plug having an annular sealing face on an exterior surface of the filling nozzle, the apparatus comprising :

a sterilization and filling head comprising a cavity, an outer sealing ring adapted to engage the tubular body sealing surface of a container, and an inner sealing ring moveable within the cavity and adapted to engage the plug sealing face of the container, the inner and outer sealing rings at least partially defining a sterilization chamber therebetween,

a sterilization fluid supply adapted to supply sterilization fluid into the sterilization chamber,

a plug extractor moveable within the inner sealing ring to engage the plug and extract the engaged plug from the tubular body into the cavity whilst maintaining sealed contact between the inner sealing ring and the plug sealing face,

filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted,

the plug extractor further being movable to reinsert the plug into the flow passage.

45. (New) An apparatus according to claim 44 wherein the inner sealing ring is adapted to seal with the plug sealing face by at least partially penetrating the plug sealing face.

46. (New) An apparatus according to claim 44 wherein said plug extractor moves within, and substantially independently of, said inner sealing ring such that as a plug is extracted from a container, the plug is urged more forcefully against the inner sealing ring.

47. (New) An apparatus according to claim 44 wherein said inner sealing ring is mounted on a moveable sleeve and wherein said plug extractor is mounted within said sleeve in a manner such that the plug extractor can move independently of the sleeve.

48. (New) An apparatus according to claim 47 wherein the sliding sleeve acts as a control valve for the filling means for controlling the flow of flowable material into a container engaged by the filling head.

49. (New) A sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage therethrough and a plug for closing the flow passage, the tubular body having an exterior sealing surface, the apparatus comprising :

a sterilization and filling head comprising a cavity, an outer sealing ring adapted to engage the tubular body sealing surface of a container, the outer sealing ring at least partially defining a sterilization chamber;

a sterilization fluid supply adapted to supply sterilization fluid into the sterilization chamber;

a plug extractor adapted to engage a plug and extract the engaged plug from the tubular body into the cavity; and

filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted;

wherein the plug extractor is adapted to re-insert the plug into the tubular body of a container after filling of the container into a position which is deeper than the initial position from which the plug was extracted.

50. (New) A sterilization and filling apparatus according to claim 49 further comprising sealing means for sealing a re-inserted plug into the tubular body of a container.

51. (New) A sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage therethrough and a removable sealing plug sealing said flow passage, the sealing plug having a side wall engaged into the passage, the tubular body having an exterior sealing surface, the apparatus comprising :

a sterilization and filling head comprising a cavity, an outer sealing ring adapted to engage the tubular body sealing surface of a container, the outer sealing ring at least partially defining a sterilization chamber;

a sterilization fluid supply adapted to supply sterilization fluid into the sterilization chamber;

a plug extractor adapted to engage a plug and extract the engaged plug from the tubular body into the cavity; and

filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted;

wherein the plug extractor is adapted to partially re-insert the plug sidewall into the tubular body of a container after filling of the container such that a portion of the plug side wall remains exposed to the sterilization chamber; and

wherein the apparatus is configured such that whilst maintaining the plug in a partially re-inserted position the sterilization fluid supply can clean the exposed surfaces of the partially inserted plug.

52. (New) An aseptic container adapted to be filled with a flowable material from a filling and sterilization head of a filling apparatus, the aseptic container having a filling opening providing an exterior sealing surface for sterilization by the filling and sterilization head, the filling opening comprising:

a tubular body having a flow passage therethrough ;

Cont
A9

a plug for aseptically sealing the flow passage, the plug having at least one engageable formation adapted to be engaged by an engaging device of the filling head for removing and replacing the plug;

a first rupturable seal for aseptically sealing the plug within the flow passage and for maintaining the interior of the container in an aseptic condition prior to filling, and

a sealing and retaining formation for aseptically sealing and retaining the plug within the flow passage and for maintaining the interior of the container in an aseptic condition once filled.

53. (New) An aseptic container according to claim 52 wherein:

the sealing and retaining formation is adapted to seal and retain the plug within the flow passage in a second position which is different from the initial position of the first rupturable seal from which the plug is arranged to be withdrawn.

54. (New) An aseptic container adapted to be filled with a flowable material from a filling and sterilization head of a filling apparatus, the aseptic container having a filling opening defining an exterior sterilizable surface for sterilization by the filling and sterilization head, the filling opening comprising:

a tubular body having a flow passage therethrough;

a plug for aseptically sealing the flow passage, an exterior portion of the plug being engageable by an engaging device of the filling head for removing and replacing the plug;

a first sealing and retaining arrangement adapted to retain the plug in the flow passage in an initial aseptically sealed position for maintaining the interior of the container in an aseptic condition prior to filling; and

a second sealing and retaining arrangement adapted to retain the plug in the flow passage in a second aseptically sealed position after the container is filled.

55. (New) An aseptic container as claimed in claim 54 wherein said first sealing and retaining arrangement includes a rupturable seal extending between the plug and the tubular body.